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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,880

12/13/2004

Shuo Lin

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/28/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/517,880

Applicant(s)

LIN, SHUO

Examiner

Valarie Bertoglio

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-9,11-18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7-9,11-18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply dated 10/06/2006 has been received. Claims 1,7,11,14 and 21 have been amended. Claims 3,6,10 and 19 have been cancelled. Claims 22-23 have been added. Claims 1,2,4,5,7-9,11-18 and 20-23 are pending and under consideration in the instant office action.

Sequence Compliance

The application is sequence compliant upon the entry of an amendment adding a sequence identifier to the description of Figure 7.

Specification

Applicant's amendment to the specification moving the priority information to the first line is noted and the objection to the specification is withdrawn.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5,11-18 and 20 remain rejected and newly added claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a method of making a diploid transgenic teleost fish comprising introducing an exogenous nucleic acid into the genome of a cultured embryonic fibroblast derived from a progenitor teleost embryo, transplanting the nucleus of the resulting transformed cell into an enucleated egg from a parental fish, wherein the parental fish is of the same species as the progenitor if fertile progeny are desired (claim 5), culturing the resultant embryo in conditions suitable for embryonic development such that a diploid transgenic fish is made and for 2) a

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method of making a teleost fish comprising obtaining a cell from a progenitor embryo, maintaining the cell in in vitro culture, transplanting the nucleus of the cultured cell into an enucleated egg from a parental fish of the same species as the progenitor and culturing the resultant embryo in conditions suitable for embryonic development such that a fertile progeny fish is made a does not reasonably provide enablement for a making any species of fish using any cell type or use of progenitor and parental fish of different species to make a fertile progeny. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is maintained for reasons of record set forth at pages 4-7 of the previous office action dated 07/06/2006.

Applicant's arguments have been fully considered and are partially persuasive as set forth below.

The claims were rejected for failing to be enabled for the full scope of the claims on 3 grounds. First, the specification does not enable the claimed methods for making viviparous species. Second, the specification is not enabling for the claimed methods using any cell type. Third, the specification does not enable making fertile progeny fish using a nucleus and an enucleated egg from different fish species.

1) The first aspect of the rejection relates to the failure of the specification to enable the claimed methods using viviparous species of fish. This aspect of the rejection is withdrawn as it relates to claims 1,2,4,5,7-9,11-18 and 20. Applicant has amended the preamble of independent claims 1 and 11 to read "oviparous teleost fish" and step (b) of claim 1 and step (c) of claim 11 require that the embryos develop externally.

This grounds of rejection is maintained and applied, however, to newly added claims 22 and 23 as set forth at pages 5-6 of the office action dated 07/06/2006. Newly added claims are not limited to oviparous species. Applicant remarks that newly added claims 22 and 23 have been drafted to recite allowable subject matter as identified by the Examiner (page 9, paragraph 2 of Applicant's Remarks). However, no recitation of oviparous is found in claims 22 or 23. Therefore, the rejection as set forth at

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pages 4-7 of the office action dated 07/06/2006 is applied to newly added claims 22 and 23, specifically for reasons of record at the paragraph bridging pages 5-6.

2) The second grounds of the rejection relating to the cell type of the donor nucleus is withdrawn as it relates to claims 1,2,4,5,7,8,9,11-18 and 20-22 as these claims are limited to use of embryonic fibroblast cells. However, claim 23 is not limited to an embryonic fibroblast cell. Therefore, the rejection set forth at pages 4-7 of the office action dated 07/06/2006 is applied to claim 23 for reasons of record set forth specifically at pages 6-7 of the office action.

3) The third grounds of the rejection involves cross-species nuclear transfer (specifically pages 7-8 of the office action dated 07/06/2006). This aspect of the rejection was applied to claims 5 and 11-20 as they require fertile offspring as a result of cross-species nuclear transfer. Claim 19 has been cancelled. Applicant has argued that nuclei can be successfully transplanted into eggs of fish within the same genus and has provided a reference indicating such [Zhu et al., Cell Research, 10:17-27, 2000; of record]. At page 20, paragraph 1, Zhu et al state that success of nuclear transfer was achieved within a genus of carp. However, success in obtaining an "offspring" is not indicative of fertility of that offspring as required by claims 5,11-18 and 20. As set forth by Sun *et al.*, cross-species nuclear transfer is effective in generating cloned fish, however, the offspring are infertile [Biology of Reproduction, 72:510-515, specifically page 513, column 1, paragraph 2]. Thus, the specification does not teach cross-species nuclear transfer as encompassed by the claims and does not enable such so as to produce fertile fish as required by claims 5,11-18 and 20. It is noted that this aspect of the rejection is not applied to claims 1,2,4,7-9, and 21-23.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The rejection of claims 6,7 and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicant's cancellation of claims 6 and 19.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 10 and 21 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, as obvious over Long *et al.* [1997, **Development**, 124:4105-4111] is withdrawn in light of Applicant's amendments to the claims. Applicant has cancelled claim 10 and has amended claim 21 to depend from claim 15, requiring that the transgene inactivate an endogenous gene, which was not taught by Long *et al.*

Thus, the following rejection is necessitated by amendment.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, as obvious over Kawakami *et al.* [2000, **Current Biology**, 10:463-466].

Claim 21 is drawn to a transgenic fish made by the nuclear transfer method of claim 15, which requires a transgene inactivate an endogenous gene by insertion.

Claim 21 is a product by process claim in which the process of creating the fish carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a transgenic fish) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed transgenic fish are met by any transgenic fish in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

Kawakami *et al.* taught a transgenic zebrafish having a retroviral transgene insertion into the endogenous hagoromo gene (paragraph bridging columns at page 463; Figure 1). The transgenic fish, as taught by Kawakami *et al.* render the claimed fish obvious, because the claimed fish is not distinguishable over the instantly claimed fish.

Thus, the teachings of Kawakami *et al.* anticipate the limitations of claim 21.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Valarie Bertoglio
Examiner
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